DETAILED ACTION

Notice to Applicant

1. This communication replaces the previous non-final office action, since the Examiner inadvertently stated that claim 1 has not been amended, but actually claim 1 had been previously amended on 03/05/2009 communication and Examiner inadvertently did not respond to Applicant's argument for this claim. Therefore, Applicant's arguments are addressed below in the section titled "Response to Arguments".

2. Claims 1-24, 193-217, 219-233, 238 (first group) and claims 234-237 (second group) had been restricted in the communication sent on 06/08/2009. In the response, the Applicant amended claims 234-237, so that these claims are dependent on claim 1, and Applicant elected the first group of invention.

3. The election received on 6/22/2009. Claims 1-24, 193-217, 219-238 remain pending in this application.

Allowable Subject Matter

4. Claims 194-200, 221-230 are allowed.

5. Claims 234-237 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The primary reason that claims 234-237 distinguish over the prior art is the inclusion of the limitations, and all of these limitations which is not found in the prior art references, of "medical device having first and second assemblies, associating the

subassemblies with a controller, using the first subassembly identifier information to associate the controller with the medical device and the selected subassembly so that the controller can communicate with the medical device and the medical device associating the communication with the first subassembly".

7. The prior art teaches "a patient identification system for relating items with patients and ensuring that an identified item corresponds to an identified patient, which monitors a nurse's time with the patient and maintain a chronology of patient events" (Gombrich; abstract, col. 3, lines 47-53), and "the description of keypad 356 includes: The amount of time between when the "COMMUNICATIONS ERROR" message has been displayed on the LCD display 354 and when the portable handheld patient terminal 320 is returned to the base station 376 is limited to 30 seconds. When a response is received from the host computer system, the time out feature is started again. The audible alarm will indicate to the operator that the communications to the host computer system is complete. If the portable handheld patient terminal is to be used again, such as for another function or to correct a red light condition, the timeout will be 30 seconds…HOLD. The "HOLD" key can only be used in specified functions. It will give the staff member the ability to hold a test order, surgical order, or a drug administration. The hold feature will give the option of: Delaying the time for the procedure/administration and the associated warnings that are given when they are late. This delay is determined by the application software of the host computer system." (Gombrich; col. 27, line 67 to col. 28, line 68).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 1, 21, 22, 23, 24, 201, 206, 207, 212, 213, 214, 215, 216, 217, 219, 220, 231, 232, 233 and 238 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombrich et al. (hereinafter Gombrich) (U.S. Patent No. 4,857,716) in view of Kerns et al. (hereinafter Kerns) (U.S. Patent No. 4,756,706).

A. Claim 1 has been amended now to recite a method for associating at least one medical device with a controller that is remote from the medical device, the method comprising the steps of:

i. providing a device identifier that includes device identifier information identifying a medical device within a communication network (Gombrich; col. 2, lines 38-47, col. 3, lines 21-30, col. 9, lines 49-65);

ii. providing a portable data collector (Gombrich; abstract, col. 8, line 56 to col. 9, line 7);

iii. with the portable data collector spatially proximate the device identifier, obtaining the device identifier information via the data collector (Gombrich; col. 2, lines 18-25, col. 8, lines 31-39, col. 15, lines 9-16, col. 22, lines 15-49);

iv. transferring the device identifier information from the data collector to the controller (Gombrich; col. 4, lines 56-64, col. 15, lines 9-16);

v. using the device identifier information to associate the controller with the medical device so that the controller can communicate with the medical device (Gombrich; col. 2, lines 35-47); and

vi. causing the controller to send a first communication to the medical device and receiving the first communication at the medical device.

Gombrich fails to expressly teach "causing the controller to send a first communication to the medical device and receiving the first communication at the medical device. However, this feature is well known in the art, as evidenced by Kerns.

In particular, Kerns discloses this feature in abstract, col. 6, line 56-63, col. 7, line 10 and Fig. 6.

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Kerns with the motivation of centrally managing medical devices (i.e. infusion pumps) for pumping and monitoring purposes (Kerns; col. 2 lines 7-13).

B. Claims 22, 201, 212, 213, 217, 219, 231 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 22, 201, 212, 213, 217, 219, 231 are rejected for the same reasons

given in the previous non-final Office Action dated 10/29/2008, and incorporated herein.

C. Claim 220 has been amended now to recite the method of claim 219 further including the step of obtaining at least one of medication information from a medication container and patient information from a patient identification device, the step of identifying at least two times including identifying:

i. The time at which the device identifier information is obtained (Gombrich; col. 2, lines 38-47, col. 3, lines 21-30);

ii. The time at which the medication information is obtained from the medication container (Gombrich; col. 15, lines 9-48);

iii. The time at which the patient information is obtained from the patient identification device (Gombrich; col. 15, lines 9-48).

D. Claim 232 has been amended to recite the same limitations as claim 1, therefore claim 232 is rejected for the same reasons given above for the rejection of claim 1, and incorporated herein.

E. Claim 233 recites the method of claim 1 wherein the controller is located in a location in one of a patient room where the medical device is located, a nurse station and a central location (Gombrich; col. 2, lines 5-32).

F. Claim 238 recites a method for associating at least one medical device with a controller that is remote from the medical device, and one of a patient and a medication, the method comprising the steps of:

i. providing a device identifier that includes device identifier information identifying a medical device within a communication network (Gombrich; col. 2, lines 5-47, col. 4, lines 56-64);

ii. providing a second identifier that includes second identification information, where the second identifier is selected from a patient identifier linked to a patient mounted device and a medication identifier linked to a medication container (Gombrich; col. 2, lines 5-47, col. 3, line 61 to col. 4, line 24, col. 4, lines 56-64);

iii. providing a portable data collector (Gombrich; abstract, col. 9, line 64 to col. 10, line 15);

iv. obtaining the device identifier information and the second identification information via the data collector (Gombrich; col. 2, lines 18-21, col. 8, lines 31-39, col. 15, lines 9-16);

v. transferring the device identifier information and the second identification information from the data collector to the controller (Gombrich; col. 4, lines 56-64, col. 15, lines 9-18);

vi. using the device identifier information to associate the controller with the medical device and associate the second identification information with control information for the medical device so that the controller can communicate with the medical device (Gombrich; col. 2, lines 5-47, col. 4, lines 56-64); and

vii. causing the controller to send a first communication to the medical device including at least a portion of the control information and receiving the first communication at the medical device.

Gombrich fails to expressly teach causing the controller to send a first communication to the medical device including at least a portion of the control information and receiving the first communication at the medical device However, this feature is well known in the art, as evidenced by Kerns.

In particular, Kerns discloses causing the controller to send a first communication to the medical device including at least a portion of the control information and receiving the first communication at the medical device (Kerns; abstract, col. 1, lines 56-67, col. 3, lines 31-46, col. 7, lines 29-43, col. 8, lines 27-31 and Fig. 1).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Kerns with the motivation of recognizing the device and make the device perform the required tasks in the network (Kerns; abstract, col. lines 29-43).

G. Claims 21, 23, 24, 206, 207, 215, 216 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 21, 23, 24, 206, 207, 215, 216 are rejected for the same reasons given in the previous non-final Office Action dated 10/29/2008, and incorporated herein.

H. Claim 214 has been amended now to recite the method of 1, wherein the medical device includes a infusion pump that includes at least first and second pump assemblies and where the device identifier information is first device identifier information associated with the first pump assembly (Gombrich; col. 2, lines 38-47, col. 3, lines 21-30, col. 9, lines 49-65), the method further including the steps of providing second device identifier information for the second pump assembly, obtaining the second device identifier information using the data collector, transmitting the second device identifier information to the controller and the controller using the first and second device identifier information to monitor operation of the first and second pump assemblies.

- The obviousness of modifying the teaching of Gombrich to include an infusion pump (as taught by Kerns) is as addressed above and in the previous office actions, in the rejection of claim 21 and incorporated herein.
- Gombrich fails to expressly teach at least first and second pump assemblies and providing second device identifier information for the second pump assembly, obtaining the second device identifier information using the data collector, transmitting the second device identifier information to the controller and the controller monitoring operation of the first and second pump assemblies. However, this feature is well known in the art, as evidenced by Kerns.

In particular, Kerns discloses at least first and second pump assemblies and providing a second address for the second pump assembly, obtaining the second address using the data collector, transmitting the second address to the controller and the controller monitoring operation of the first and second pump assemblies (Kerns; abstract, col. 2, lines 49-55).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Kerns with the motivation of providing a versatile tool for the central management of multiple intravenous infusions (Kerns; col. 7, lines 36-45).

10. Claims 2-20, 193, 202, 203, 208-211 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombrich et al. (hereinafter Gombrich) (U.S. Patent No. 4,857,716), Kerns et al. (hereinafter Kerns) (U.S. Patent No. 4,756,706) and further in view of Examiner's official notice.

A. As per claim 2, Gombrich discloses the method of claim 1 wherein the obtaining step is via wireless communication (Gombrich; col. 4, lines 56-64, col. 15, lines 9-48).

- While Gombrich does not explicitly disclose that a wireless communication network is being used in transferring step, Official Notice is taken that wireless connections to various communication networks, such as telephone, television, and computer networks, are

old and well known. Wireless communications between computers and medical devices all were well known and widely used within our society at the time of the present invention and have been developed and used to allow the users more mobility. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to connect the terminals in Gombrich using known wireless technology. One would have been motivated to use wireless technology to connect the devices and a computer, in order to allow the medical devices and the controller (or a remote computer) has a faster communication.

B. Claim 3 has been amended now to recite the method of claim 1 wherein the first communication is a wireless communication.

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

C. As per claim 4, Gombrich discloses the method of claim 3 wherein the step of sending the first communication includes the step of transmitting a controller address of the controller within the communication network (Gombrich; col. 4, lines 56-64, col. 15, lines 9-48).

D. As per claim 5, Gombrich discloses the method of claim 3 further including the step of, in response to the first communication, causing the medical device to perform a safety function (Gombrich; col. 15, lines 49 to col. 16, line 2).

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

E. As per claim 6, Gombrich discloses the method of claim 5 wherein the medical device includes an indicator and the safety function includes activating the indicator (Gombrich; col. 15, lines 49 to col. 16, line 2).

F. As per claim 7, Gombrich discloses the method of claim 5 wherein the medical device includes a transmitter and the safety function includes causing the medical device to transmit a second communication responsive to the first communication (Gombrich; col. 15, lines 9 to col. 16, line 2).

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

G. As per claim 8, Gombrich discloses the method of claim 7 wherein the second communication includes the status of the medical device (Gombrich; col. 15, lines 9 to col. 16, line 2).

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

H. As per claim 9, Gombrich discloses the method of claim 7 wherein the second communication is transmitted to the controller (Gombrich; col. 15, lines 9 to col. 16, line 2, col. 16, lines 28-50).

I. Claim 10 has been amended now to recite the method of claim 5 further including the steps of storing a first patient information set in the medical device indicating information related to a patient for which the medical device has been provided and storing a second patient information set in the controller indicating information related to a patient and wherein the step of causing the controller to send a first communication includes the step of transmitting the second patient information set to the medical device, the step of receiving includes receiving the first patient information subset at the medical device and wherein the step of causing the device to perform a first safety function includes comparing the first and second patient information sets (Gombrich; col. 8, line 31 to col. 9, line 7, col. 15, lines 9-48).

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

J. As per claim 11, Gombrich discloses the method of claim 10 further including the step of providing an indicator on the medical device and wherein the step of causing the device to perform a safety function further includes the step of, when the first and second patient information sets are different, activating the indicator (Gombrich; col. 15, line 9 to col. 16, line 2).

K. As per claim 12, Gombrich discloses the method of claim 10 wherein the step of storing the first patient information set on the medical device includes the step of storing the first patient information set on an information device, the information device being one of a medication delivery container, a patient mounted device and a physician's computing device, establishing a communication link between the information device and the medical device and transferring the first patient information set from the information device to the medical device (Gombrich; col. 2, lines 5-32, lines 38-47).

L. As per claim 13, Gombrich discloses the method of claim 12 wherein the information device is an IV bag (Gombrich; col. 2, lines 38-47).

M. As per claim 14, Gombrich discloses the method of claim 10 wherein the step of storing the first patient information set on the medical device includes the step of providing a medical device interface and entering the first patient information set via the interface device (Gombrich; col. 12, line 64 to col. 13, line 31).

N. As per claim 15, Gombrich discloses the method of claim 10 wherein each of the medical device and the controller are system devices, the method further includes the step of providing at least a third system device and wherein the step

of storing the second patient information set on the controller includes the step of storing the second patient information set on the third system device, establishing a communication link between the third system device and the controller and transferring the second patient information set from the third system device to the controller (Gombrich; col. 12, line 64 to col. 13, line 31, col. 15, lines 9-48).

O. As per claim 16, Gombrich discloses the method of claim 15 wherein the step of providing the third system device includes the step of providing a patient mounted device (Gombrich; col. 12, line 64 to col. 13, line 31).

P. As per claim 17, Gombrich discloses the method of claim 16 wherein the step of providing a patient mounted device includes providing a wrist band (Gombrich; col. 12, line 64 to col. 13, line 31).

Q. As per claim 18, Gombrich discloses the method of claim 10 wherein the step of storing the second patient information set on the controller includes the step of providing a controller interface and entering the second patient information set via the interface device (Gombrich; col. 8, lines 31-55).

R. As per claim 19, Gombrich discloses the method of claim 7 further including the steps of storing a first patient information set in the medical device indicating information related to a patient for which the medical device has been provided and storing a second patient information set in the controller indicating information related to a patient and wherein the step of causing the device to perform a safety function includes the steps of transferring a second

communication to the controller including the first patient information set and comparing the first and second patient information sets (Gombrich; col. 15, line 9 to col. 16, line 2).

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

S. Claim 20 has been amended now to recite the method of claim 19 further including the step of providing an indicator on the medical device and wherein the step of causing the device to perform a safety function further includes the step of, when the first and second patient information sets are different, activating the indicator (Gombrich; col. 15, line 9 to col. 16, line 2).

T. Claim 193 has been amended now to recite the method of claim 1, wherein the obtaining step includes reading a bar code on the medical device and the transferring step includes transferring the device identifier information (Gombrich; col. 2, lines 38-47, col. 3, lines 21-30, col. 9, lines 49-65, col. 15, lines 9-48).

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

U. Claim 202 has been amended now to recite the method of claim 3 wherein the device identifier information includes a medical device address (Gombrich; col. 2, lines 38-47, col. 3, lines 21-36, col. 9, lines 49-65, col. 15, lines 9-48) and the method further including the step of using the medical device address to send the first wireless communication.

- The obviousness of modifying the teaching of Gombrich to include a wireless communication (as rejected by Official Notice) is as addressed above in the rejection of claim 2 and incorporated herein.

V. Claims 203, 208-211 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 203, 208-211 are rejected for the same reasons given in the previous non-final Office Action dated 10/29/2008, and incorporated herein.

11. Claims 204-205 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gombrich et al. (hereinafter Gombrich) (U.S. Patent No. 4,835,372), Kerns et al. (hereinafter Kerns) (U.S. Patent No. 4,756,706), Examiner's Official Notice, and further in view of Engleson et al. (hereinafter Engleson) (U.S. Patent No. 5,781,442).

A. As per claim 204, Gombrich discloses the method of claim 203. Claim 204 further including the steps of providing at least a second medical device that is not associated with the controller wherein when any medical device transmits information that is received by the controller, the controller determines if the controller is associated with the transmitting device and wherein the controller

only uses received information from associated medical devices and ignores received information from devices that are not affiliated with the controller.

- Gombrich fails to expressly teach a second medical device and the controller determines if the controller is associated with the transmitting device and wherein the controller only uses received information from associated medical devices and ignores received information from devices that are not affiliated with the controller. However, this feature is well known in the art, as evidenced by Engleson.

  In particular, Engleson discloses a second medical device and the controller determines if the controller is associated with the transmitting device and wherein the controller only uses received information from associated medical devices and ignores received information from devices that are not affiliated with the controller (Engleson; abstract, col. 2, lines 53-66, figure 2). Examiner considers that since Engleson teaches plural of infusion pumps and further identifying and verifying correct medication for the patient, therefore Engleson is matching the pumps with a controller or a controlling computer for identification and verification purposes and ignores other information received from other devices that do not match.

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Engleson with the motivation of increasing the safety and security.

B. Claim 205 has been amended now to recite the method of claim 1 wherein the medical device is a first medical device and the device identifier information of the first medical device is first device identifier information the method further including the steps of providing a first indicator that is associated with the first medical device (Gombrich; col. 9, lines 39-47, lines 64-66).

- Gombrich fails to expressly teach a second medical device and the controller determines if the controller is associated with the transmitting device and wherein the controller only uses received information from associated medical devices and ignores received information from devices that are not affiliated with the controller. However, this feature is well known in the art, as evidenced by Engleson.

  In particular, Engleson discloses providing a second medical device with a second device address and a second indicator, obtaining the second device address via the data collector; transferring the second device address from the data collector to the controller and associating the controller with the second medical device so that

the controller can communicate with the second medical device (Engleson; abstract, col. 2, line 39 to col. 3, line 5).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Engleson with the motivation of increasing the safety and security.

- Gombrich fails to expressly teach using the controller to select information related to the first medical device and using the first medical device identifier information to send a signal to the first medical device, receiving the signal by the first medical device and using the signal to activate the first indicator. However, this feature is well known in the art, as evidenced by Kerns.

  In particular, Kerns discloses this limitation in col. 2, lines 49-55, col. 3, lines 34-41, col. 4, lines 43-50, and in col. 7, line 63 to col. 8, line 10.

  It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Kerns with the motivation of to provide a centrally-managed integral set for pumping and monitoring purposes.

Response to Arguments

12. Applicant's arguments filed 03/05/2009 have been fully considered but they are not persuasive. Applicant's arguments will be addressed below in the order in which they appear.

A. In response to Applicant's argument about Gombrich does not teach "a controller that communicates with medical devices"; Examiner respectfully submits that Gombrich teaches "Yet another object of the present invention is the provision of a portable handheld terminal providing wireless communication by use of an electromagnetic transceiver to a base station transceiver unit. The base station being interconnected to a host central computer system so as to provide real time or near real time communication system so as to provide real time or near real time communication between the portable handheld terminal and the host central computer system." In col.4, lines 56-64. Therefore Examiner considers that the base station transceiver unit is the controller. Gombrich fails to expressly teach "causing the controller to send a first communication to the medical device and receiving the first communication at the medical device". However, this feature is well known in the art, as evidenced by Kerns and explained above in the rejection of claim 1.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DILEK B. COBANOGLU whose telephone number is (571)272-8295. The examiner can normally be reached on 8-4:30.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on 571-272-6787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dilek B Cobanoglu/
Examiner, Art Unit 3626
4/6/2010